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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/022,859	12/20/2001	J. Michael Ramstack	000166.0108-US01	1415

26853 7590 12/01/2003

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EXAMINER	
PULLIAM, AMY E	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 12/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/022,859	RAMSTACK ET AL.	
	Examiner	Art Unit	
	Amy E Pulliam	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *65-115* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *65-115* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Declaration, Fee, and Information Disclosure Statement, all received by the Office March 20, 2002, as well as the Preliminary Amendment and Supplemental Information Disclosure Statement, received July 31, 2003.

The previous action, mailed July 24, 2003, has been withdrawn, as it did not consider the Preliminary Amendment filed by Applicant.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 65-115 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,650,173 to Ramstack *et al.*.

Ramstack *et al.* teach a process for preparing biodegradable microspheres comprising a polymer and an active. More specifically, the process entails blending at least two solvents and using the blend to dissolve the active agent and the polymer. The solvent blend containing the active and the polymer is then dispersed in an aqueous solution to form droplets. The resulting emulsion is then added to an aqueous extraction medium whereupon the biodegradable microparticles are formed (c 3, l 27-40). Ramstack *et al.* also teach that the polymer can be selected from polyglycolic acids and polylactic acids (c 7, l 28-35). Furthermore, Ramstack *et al.* teach that the solvent system which gives the most improved microparticle quality is ethyl acetate and benzyl alcohol (c 8, l 50-52). Lastly, Ramstack *et al.* teach that the active agent can be risperidone (c 26, claim 12).

Ramstack *et al.* do not specifically teach that the microparticles are "maintained" at "a certain temperature" for "a certain period of time." However, it is the position of the examiner that the cited reference still renders applicant's claimed process obvious. First, many of the claims do not specify a temperature . Second, even the claims which do specify a temperature, specify that it be between 20 to 25° C. The examiner points out that this temperature range includes average room temperature. Therefore, all that is required to fulfill the limitations of applicant's instant claims is that after the formation of the microparticles, and prior to their use in a pharmaceutical composition, they are placed into any type of container in a normal room, and held there until they are needed for further pharmaceutical processing.

Additionally, it is within the ordinary skill of the pharmaceutical art to set aside a recently made batch of microparticles, allowing them to thoroughly dry, prior to using the microparticles in any further formulations. Additionally, it is within the knowledge of the ordinary artisan that increased dryness equals increased flowability.

Also, absent evidence to the contrary, there has been no criticality placed on the length of time the microparticles are maintained at this temperature, or on the flowability index, or the angle of repose. It appears, from the teachings of both the cited reference and Applicant's teachings, that the two are achieving the same end result. Furthermore, regarding the flowability index and the angle of repose, the Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Furthermore, claims 91-93 and 100 are product by process claims. According to the MPEP section 2113, "even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production, If the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even

though the prior art was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed.Cir. 1985).

Therefore, one of ordinary skill in the art would have been motivated to use the process disclosed by Ramstack *et al.* to make microparticles, and then set aside these microparticles, prior to using them, to ensure thorough dryness. The expected result would be microparticles which are thoroughly dried prior to use, and therefore have increased flowability. Therefore, applicant's steps claiming maintaining the microparticles at a conditioning temperature for a period of time would have been obvious to one of ordinary skill in the art at the time the invention was made.

Claims 65-86, 88-111, and 113-115 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Use of polylactic acid for the preparation of microparticulate drug delivery systems" by Conti (hereafter Conti).

Conti discloses several processes for preparing microparticles. One of these processes is emulsion solvent extraction, which involves emulsifying, in an aqueous medium, a polymer previously dissolved in a volatile organic solvent. The drug to be incorporated is either dissolved or suspended in the polymer solution. As the emulsion is formed, it is poured into a diluent phase and stirred. Microspheres are obtained by extraction of the polymer solvent. Conti further teaches that solid microspheres are recovered by filtration, washed and dried under vacuum (page 161). Additionally, Conti teaches that polylactic acid can be used as the polymer (throughout).

Conti do not specifically teach that the microparticles are "maintained" at "a certain temperature" for "a certain period of time." However, it is the position of the examiner that the cited reference still renders applicant's claimed process obvious. First, many of the claims do not specify a temperature or a time frame. Second, even the claims which do specify a temperature, specify that it be between 20 to 25° C. The examiner points out that this temperature range includes average room temperature. Therefore, all that is required to fulfill the limitations of applicant's instant claims is that after the formation of the microparticles, and prior to their use in a pharmaceutical composition, they are placed into any type of container in a normal room, and held there until they are needed for further pharmaceutical processing.

Additionally, it is within the ordinary skill of the pharmaceutical art to set aside a recently made batch of microparticles, allowing them to thoroughly dry, prior to using the microparticles in any further formulations. Additionally, it is within the knowledge of the ordinary artisan that increased dryness equals increased flowability.

Also, absent evidence to the contrary, there has been no criticality placed on the length of time the microparticles are maintained at this temperature, or on the flowability index, or the angle of repose. It appears, from the teachings of both the cited reference and Applicant's teachings, that the two are achieving the same end result. Furthermore, regarding the flowability index and the angle of repose, the Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught

by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Furthermore, claims 91-93 and 100 are product by process claims. According to the MPEP section 2113, "even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production, If the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior art was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed.Cir. 1985).

Therefore, one of ordinary skill in the art would have been motivated to use the process disclosed by Conti to make microparticles, and then set aside these microparticles, prior to using them, to ensure thorough dryness. The expected result would be microparticles which are thoroughly dried prior to use, and therefore have increased flowability. Therefore, applicant's steps claiming maintaining the microparticles at a conditioning temperature for a period of time would have been obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A. Pulliam
Patent Examiner
Art Unit 1615
November 18, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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